IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

GEORGE RUSSELL-NELSON, et al.,

Plaintiffs,

v.

MEDTRONIC, INC., et al.,

Defendants.

Civil No. 07-1969 (GAG)
(Lead Case)

Civil No. 07-1971 (GAG)
(Member Case)

Civil No. 07-1972 (GAG)
(Member Case)

Civil No. 07-2014 (GAG)
(Member Case)

Civil No. 07-2021 (GAG)
(Member Case)

Civil No. 07-2064 (GAG)
(Member Case)

U.S.A.J.

ORDER FOR THE PRESERVATION OF EVIDENCE

Pursuant to the Court's duty to supervise pretrial proceedings in this case, including discovery, and pursuant to the Court's inherent power, the Court hereby Orders, effective immediately, that Medtronic, Inc., Medtronic Puerto Rico, Inc. (n/k/a Medtronic International Technology, Inc.), and Medtronic Puerto Rico Operations Co., their officers and employees (collectively, "Medtronic") and all named Plaintiffs (collectively, "the Parties") comply with the following directives relating to the preservation of evidence in the above captioned matter:

A. **Definitions**

"Sprint Fidelis Leads" means those leads marketed by Medtronic under the following model numbers:

1. the 6949 LFJ extendable/retractable screw fixation (S) model;

2. the 6948 LFH tined fixation (T) model;

3. the 6931 LFT S fixation model; and

4. the 6930 LFK T fixation model.

B. Devices Subject to this Order

The provisions of this Order shall pertain to the following:

1. **Explanted Sprint Fidelis Leads**

The provisions of this Order shall pertain to Medtronic Sprint Fidelis leads that have been returned to Medtronic after being explanted from a patient ("Explanted Sprint Fidelis Leads").

2. **Other Sprint Fidelis Leads**

The provisions of this Order shall also pertain to Medtronic Sprint Fidelis leads that have been the subject of research in the laboratory without having been implanted (collectively, "Other Sprint Fidelis Leads").

3. **Returned Implanted Products**

The provisions of this Order shall also pertain to any other Medtronic products that have been returned to Medtronic that, through reasonable efforts, can be identified as having been implanted together with Sprint Fidelis Leads, including other lead models, implantable cardioverter defibrillators ("ICDs"), and implantable pulse generators ("IPGs") (collectively, "Returned Implanted Products").

C. Testing and Analysis

The Court will specifically allow the following:

1. **Non-Destructive Testing and Analysis**. Non-destructive testing and analysis by Medtronic of Explanted Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products is allowed. Where appropriate, this testing and analysis of such

products may include, but is not limited to: (1) reprogramming to turn the ventricular fibrillation detection therapy "off," if it is programmed "on"; (2) interrogation utilizing a Medtronic programmer; (3) recording continuity and electrical testing; (4) creating a Save-to-Disk file of data extracted from such products; (5) importing the Save-to-Disk file to any associated data system, including but not limited to Medtronic internal regulatory reporting systems; (6) photographing; and (7) decontaminating and sterilizing. The information obtained using the Medtronic programmer and the Save-to-Disk process shall be preserved. All Explanted Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products shall be retained.

2. **Destructive Testing and Analysis**. In addition to the testing allowed in Paragraph 1, above, Medtronic may perform destructive testing and analysis of Explanted Sprint Fidelis Leads, Other Sprint Fidelis Leads, and Returned Implanted Products, provided that: (i) Medtronic maintains a record, in writing or electronically, of such testing and analysis and, where possible, a Save-to-Disk file of data extracted from Returned Implanted Products; and (ii) Medtronic agrees, as part of said testing and analysis, to make the results available to Plaintiffs' counsel. To the extent that Medtronic determines that destructive testing and analysis of an Explanted Sprint Fidelis Lead is required, it shall take and preserve a photograph of the Lead before such destructive testing and analysis commences and it shall take and preserve another photograph of that Lead after such destructive testing and analysis has concluded. Medtronic also agrees to investigate the possibility of creating additional device data capture methods that might be able to be used to extract and preserve data on certain Returned Implanted Products that may not be captured by the Save-to-Disk procedure. The Parties agree that, at some point after the Judicial Panel on Multidistrict Litigation issues an order deciding pending motions to transfer and consolidate these actions with other actions filed in other venues, the

Parties will meet and confer regarding issues concerning the possible collection and translation of such data.

D. Notice Requirements

1. Medtronic shall not conduct any destructive testing or analysis of Explanted Sprint Fidelis Leads from the named plaintiffs in this action until and unless: (1) the patient whose leads it was or his/her counsel have been notified of the plans for the destructive testing or analysis; and (2) his/her counsel (or his/her representative as designated to Medtronic) has been provided with an opportunity to observe, in person, the destructive testing or analysis. Such notice and the opportunity to observe the destructive testing or analysis is not required to be given before the destructive testing or analysis is conducted on Explanted Sprint Fidelis Leads from putative class members, with the exception of named plaintiffs in this action.

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2. Prior to any destructive testing or analysis of Explanted Sprint Fidelis Leads from the named plaintiffs in this action, his/her counsel shall be provided with: (1) a proposed protocol for conducting the destructive testing or analysis; and (2) reasonable notice of the time and place for the destructive testing to be conducted. Such notice and the proposed protocol for conducting the destructive testing or analysis is not required to be given before destructive testing or analysis is conducted on Explanted Sprint Fidelis Leads from putative class members, with the exception of named plaintiffs in this action.

3. Counsel for a named plaintiff in this action shall be provided with copies of materials created, electronically or otherwise, that memorialize the results of the destructive testing and analysis performed by Medtronic on the named plaintiff's Explanted Sprint Fidelis Lead.

E. Surgically Removed Sprint Fidelis Leads in Plaintiffs' Possession

1. In the event Plaintiffs or their agents retain any surgically removed Sprint

Fidelis Leads, Plaintiffs must notify Medtronic of the Model and Serial number of the surgically removed Sprint Fidelis Leads. Plaintiffs shall notify Medtronic of said retention and shall not conduct any destructive testing or analysis of the surgically removed Sprint Fidelis Leads, until and unless Medtronic and its counsel have been notified of the plans for the destructive testing or analysis and provided an opportunity to observe, in person, the destructive testing or analysis.

2. Prior to any destructive testing or analysis, Plaintiffs must (i) provide Medtronic with a proposed protocol for conducting the destructive testing or analysis, (ii) agree to allow a representative of Medtronic to be present at the destructive testing or analysis and provide reasonable notice of the time and place for the destructive testing to be conducted, and (iii) provide Medtronic with copies of materials created, electronically or otherwise, that memorialize the results of the destructive testing and analysis performed by or on behalf of Plaintiffs or their agents.

3. Medtronic has a right to perform an in-person inspection of Sprint Fidelis Leads following any testing done by or on behalf of Plaintiffs or their agents and a right to conduct its own analysis and testing of any such leads upon reasonable notice, and subject to the provisions of Section D above or as otherwise agreed by the Parties.

4. Plaintiffs, at their option, can return to Medtronic any surgically removed Sprint Fidelis Leads. Such Leads should be returned to a representative of Medtronic whom Medtronic shall designate in writing within ten (10) business days of the entry of this Order. Plaintiff shall maintain chain of custody information for such Leads up to and including their return to Medtronic. Once received by Medtronic, such Leads will be governed by the terms and conditions of this Order.

F. Return to Medtronic of Other Surgically Removed Devices in Plaintiffs' Possession

1. Any Plaintiff in possession of surgically removed Medtronic products, other than Explanted Sprint Fidelis Leads, that were implanted together with Sprint Fidelis Leads must return such devices, if they have not done so already, within thirty (30) days of the date of this Order, to a representative of Medtronic that shall be designated in writing by Medtronic within ten (10) days of entry of this Order. Plaintiff shall maintain chain of custody information for such devices.

2. Each device received pursuant to Paragraph 1, above, shall be considered to be Returned Implanted Products, as defined above in Section B and will be subject, as appropriate, to the testing and analysis provisions detailed above in Section C and the notice provisions detailed above in Section D.

3. Any Plaintiff who was, but no longer is, in possession of surgically removed Medtronic products, other than Explanted Sprint Fidelis Leads, that were implanted together with Sprint Fidelis Leads must provide to Medtronic, within thirty (30) days of the date of this Order, any and all information related to the current whereabouts or status of that lead or product, unless the lead or product is in Medtronic's possession.

G. Other Devices

Medtronic may continue its customary device testing and analysis for any device not described herein.

H. Preservation of Documents, Electronically Stored Information, and Tangible Things

The Parties shall take good faith reasonable steps, including due diligence, to preserve all documents, electronically stored information, and tangible things within their possession, custody, or control that contain information that is relevant to the allegations and

defenses in this action or that is reasonably calculated to lead to the discovery of admissible evidence in this action.

December 12th, 2007 by: U.S.D.J.
Judge Gustavo A. Gelpi